

EXHIBIT 1

UNITED STATES INTERNATIONAL TRADE COMMISSION

Washington, D.C.

In the Matter of

**CERTAIN LIGHT-BASED
PHYSIOLOGICAL MEASUREMENT
DEVICES AND COMPONENTS THEREOF**

Inv. No. 337-TA-1276

FINAL INITIAL DETERMINATION ON VIOLATION OF SECTION 337

Administrative Law Judge Monica Bhattacharyya

(January 10, 2023)

Appearances:

For Complainants Masimo Corporation and Cercacor Laboratories, Inc.:

Stephen C. Jensen, Joseph R. Re, Irfan A. Lateef, Sheila N. Swaroop, Ted M. Cannon, Brian C. Claassen, Alan G. Laquer, Kendall M. Loebbaka, Daniel C. Kiang, and Douglas B. Wentzel of Knobbe, Martens, Olson & Bear, LLP in Irvine, CA; William R. Zimmerman and Jonathan E. Bachand of Knobbe, Martens, Olson & Bear, LLP in Washington, DC; Carol Pitzel Cruz of Knobbe, Martens, Olson & Bear, LLP in Seattle, WA; and Karl W. Kowallis and Matthew S. Friedrichs of Knobbe, Martens, Olson & Bear in New York, NY.

For Respondent Apple Inc.:

Mark D. Selwyn of Wilmer Cutler Pickering Hale and Dorr LLP in Palo Alto, CA; Joseph J. Mueller, Richard Goldenberg, and Sarah R. Frazier of Wilmer Cutler Pickering Hale and Dorr LLP in Boston, MA; and Michael D. Esch and David Cavanaugh of Wilmer Cutler Pickering Hale and Dorr LLP in Washington, DC.

Pursuant to the Notice of Investigation (EDIS Doc. ID 749538), 86 Fed. Reg. 46275-76 (Aug. 18, 2021), and Commission Rule 210.42, this is the administrative law judge's final initial determination on violation in the matter of *Certain Light-Based Physiological Measurement Devices and Components Thereof*, Commission Investigation No. 337-TA-1276. 19 C.F.R. § 210.42(a)(1)(i).

For the reasons discussed herein, it is the undersigned's final initial determination that there has been a violation of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, in the importation into the United States, the sale for importation, and/or the sale within the United States after importation of certain wearable electronic devices with light-based pulse oximetry functionality and components thereof by reason of infringement of certain claims of U.S. Patent No. 10,945,648.

It is also the undersigned's final initial determination that there has been no violation of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, in the importation into the United States, the sale for importation, and/or the sale within the United States after importation of certain wearable electronic devices with light-based pulse oximetry functionality and components thereof with respect to U.S. Patent Nos. 10,912,501, U.S. Patent No. 10,912,502, U.S. Patent No. 10,687,745, and U.S. Patent No. 7,761,127.

TABLE OF CONTENTS

I.	BACKGROUND.....	1
A.	Procedural History	1
B.	The Parties	3
C.	Asserted Patents	4
D.	Products at Issue	4
E.	Witness Testimony.....	5
II.	JURISDICTION AND IMPORTATION.....	8
A.	Personal Jurisdiction	8
B.	<i>In Rem</i> Jurisdiction and Importation.....	8
III.	LEGAL STANDARDS.....	8
A.	Infringement.....	8
B.	Invalidity	11
C.	Inequitable Conduct	16
D.	Domestic Industry	17
IV.	POEZE PATENTS	19
A.	Specification	20
B.	Asserted claims	21
C.	Level of Ordinary Skill in the Art.....	25
D.	Claim Construction	26
E.	Infringement.....	33
F.	Domestic Industry—Technical prong.....	55
G.	Invalidity – Anticipation/Obviousness	88
H.	Invalidity – Written Description and Enablement	156
I.	Prosecution Laches and Unclean Hands	170
V.	U.S. PATENT NO. 10,687,745.....	174
A.	Specification	174
B.	Claims	176
C.	Level of Ordinary Skill in the Art.....	179
D.	Claim Construction	179
E.	Infringement.....	180
F.	Domestic Industry—Technical Prong.....	199
G.	Invalidity – Obviousness.....	209
H.	Invalidity – Written Description and Enablement	241
I.	Prosecution Laches	245
VI.	U.S. PATENT NO. 7,761,127.....	246
A.	Specification	247
B.	Claims	248
C.	Level of Ordinary Skill in the Art.....	249
D.	Claim Construction	250
E.	Infringement.....	259
F.	Domestic Industry—Technical Prong.....	273
G.	Invalidity	283
VII.	DOMESTIC INDUSTRY – ECONOMIC PRONG (MASIMO WATCH)	301
A.	The “Masimo Watch” Articles.....	301

B. Disputed Background Issues Regarding Domestic Industry Investments 302

C. Domestic Industry Existing at the Time of the Complaint 305

D. Domestic Industry in the Process of Being Established 319

VIII. DOMESTIC INDUSTRY – ECONOMIC PRONG (’127 PATENT)..... 324

A. Domestic Industry Existing at the Time of the Complaint 324

B. Domestic Industry in the Process of Being Established 326

C. Asserted Domestic Industry Expenditures..... 327

IX. CONCLUSIONS OF LAW..... 335

I. BACKGROUND

A. Procedural History

The Commission instituted this investigation in response to a complaint filed by Complainants Masimo Corporation and Cercacor Laboratories, Inc. on June 30, 2021, with an amended complaint filed on July 12, 2021 (the “Amended Complaint,” EDIS Doc. ID 746186), and supplemented on July 19, 2021. Notice of Investigation at 1, EDIS Doc. No. 749538 (Aug. 13, 2021); 86 Fed. Reg. 46275-76 (Aug. 18, 2021). The complaint, as amended, alleges violations of section 337 of the Tariff Act of 1930, as amended, by reason of infringement of certain claims of U.S. Patent No. 10,912,501 (“the ’501 patent”), U.S. Patent No. 10,912,502 (“the ’502 patent”), U.S. Patent 10,945,648 (“the ’648 patent”), U.S. Patent No. 10,687,745 (“the ’745 patent”), and U.S. Patent No. 7,761,127 (“the ’127 patent”). *Id.* The Commission ordered institution of this investigation to determine “whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain products . . . by reason of infringement of one or more of claims 1-9 and 11-30 of the ’501 patent; claims 1-2, 4-6, 8-12, 14-22, 24-26, and 28-30 of the ’502 patent; claims 1-17 and 19-30 of the ’648 patent; claims 1-6, 8-9, 11, 14, 20-24, and 26-27 of the ’745 patent; and claims 7-9 of the ’127 patent; and whether an industry in the United States exists as required by subsection (a)(2) of section 337.” *Id.* at 2. The investigation was instituted upon publication of the Notice of Investigation in the *Federal Register* on Monday, August 18, 2021. 86 Fed. Reg. 46275-76.

Respondent Apple Inc. filed a response to the Amended Complaint and Notice of Investigation on September 7, 2021 (the “Response to Complaint”), disputing Complainants’

allegations with respect to infringement and domestic industry and asserting affirmative defenses of invalidity and unenforceability. *See* EDIS Doc. ID 752521.¹

Pursuant to Order No. 3 (Sept. 1, 2021), the target date of this investigation was set to be December 16, 2022. On September 13, 2021, the investigation was assigned by then Chief Administrative Law Judge Bullock to the undersigned. *See* Notice to the Parties, EDIS Doc. ID 751531 (Sept. 13, 2021). Pursuant to Order No. 5 (Sept. 22, 2021), the target date was extended to January 16, 2023. *See* Comm'n Notice (Oct. 12, 2021), EDIS Doc. ID 754020.

A technology tutorial and *Markman* hearing was held on February 17, 2022. *See Markman* Tr., EDIS Doc. ID 763489.²

Pursuant to Order No. 25 (Mar. 23, 2022), Complainants withdrew their allegations of infringement with respect to claims 2, 4, 5, 7, 11, 16, 19, 20, and 22-30 of the '501 patent, claims 1-2, 4-6, 8-12, 14-18, 20, 25, and 26 of the '502 patent, claims 3, 4, 6, 7, 9, 10, 13-17, 19, 22, and 25-28 of the '648, and claims 1, 3-6, 8, 11, 14, 20-24, and 26 of the '745 patent. *See* Comm'n Notice, EDIS Doc. ID 768023 (Apr. 12, 2022). Pursuant to Order No. 33 (May 20, 2022), Complainants withdrew their allegations of infringement with respect to claims 1, 3, 6, 8, 9, 13-15, 17, 18, and 21 of the '501 patent, claims 19, 21, 24, 29, and 30 of the '502 patent, claims 1, 2, 5, 8, 11, 20, 21, 23, and 29 of the '648, and claim 2 of the '745 patent. *See* Comm'n Notice, EDIS Doc. ID 772826 (Jun. 10, 2022).

¹ The affirmative defenses based on inequitable conduct were stricken pursuant to Order No. 9 (Dec. 20, 2021), and Respondent was subsequently granted leave to add certain inequitable conduct defenses pursuant to Order No. 23 (Mar. 23, 2022).

² All of the claim construction disputes raised at the *Markman* hearing were subsequently mooted by the withdrawal of asserted claims or by agreement of the parties. *See infra*.

An evidentiary hearing was held on June 6-10, 2022. The parties filed initial post-hearing briefs on June 27, 2022, and filed post-hearing reply briefs on July 11, 2022. Additional exhibits were admitted pursuant to Order No. 50 (Jun. 16, 2022) and Order No. 56 (Aug. 31, 2022). The hearing transcript was amended pursuant to Order No. 51 (Jun. 23, 2022) and Order No. 52 (Jun. 27, 2022). The parties' post-hearing briefs were amended pursuant to Order No. 54 (Jul. 14, 2022), Order No. 55 (Jul. 14, 2022), and Order No. 57 (Aug. 31, 2022).

Pursuant to Order No. 58 (Sept. 12, 2022), Order No. 59 (Oct. 24, 2022), and Order No. 61 (Dec. 9, 2022), the target date was extended to May 10, 2023. *See* Comm'n Notice, EDIS Doc. ID 787448 (Jan. 6, 2023).

B. The Parties

1. Complainants

The Complainants are Masimo Corporation ("Masimo") and Cercacor Laboratories, Inc. ("Cercacor") (collectively, "Complainants"). Notice of Investigation at 2. Masimo and Cercacor are both Delaware corporations having their principal places of business in Irvine, California. Complaint ¶ 9. Masimo is the owner of the '501 patent (JX-0001), '502 patent (JX-0002), '648 patent (JX-0003), and '745 patent (JX-0009). *Id.* ¶ 4. Cercacor is the owner of the '127 patent (JX-0007). *Id.* Masimo and Cercacor have rights to each of the asserted patents through a cross-licensing agreement. *Id.* ¶¶ 4, 77; CX-1612C.

2. Respondent

The Respondent is Apple Inc. ("Apple"). Notice of Investigation at 2. Apple is a California corporation having its principal place of business in Cupertino, California. Response to Complaint ¶ 21.

C. Asserted Patents

The '501 patent, '502 patent, and '648 patent share a common specification, claiming priority to an application filed on July 3, 2008. JX-0001; JX-0002; JX-0003. These patents are entitled “User-Worn Device for Noninvasively Measuring a Physiological Parameter of a User,” naming inventors Jeroen Poeze *et al.*, and are referenced herein as the “Poeze patents.” *Id.*

The '745 patent is entitled “Physiological Monitoring Devices, Systems, and Methods,” and claims priority to an application filed on June 28, 2016, naming inventor Ammar Al-Ali. JX-0009.

The '127 patent is entitled “Multiple Wavelength Sensor Substrate” and issued from an application filed on March 1, 2006, naming inventors Ammar Al-Ali *et al.* JX-0007.

D. Products at Issue

The products at issue are “wearable electronic devices with light-based pulse oximetry functionality and components thereof.” Notice of Investigation at 2.

1. Accused Products

Complainants accuse Apple Watch products of infringing the asserted patents, including the Apple Watch Series 6, the Apple Watch Series 7, and certain prototype Apple Watch products [REDACTED] (“Next Generation Apple Watches”). CIB at 37-39. Apple has stipulated to the importation of the Apple Watch Series 6, Apple Watch Series 7, and Next Generation Apple Watches (collectively, the “Accused Products”). *See* CX-0128C (Stipulation Regarding Importation and Inventory) at ¶¶ 2-4; CX-1259C (Stipulation Relating to Next-Generation Watches) at ¶¶ 5-6. The parties have stipulated that the Accused Products are materially identical for the purposes of infringement in this investigation. *See* Joint Stipulation of Facts at ¶¶ 11-13, EDIS Doc. ID 770692 (May 13, 2022); CX-1259C at ¶¶ 7-8.

significance where a domestic industry is based on “core manufacturing activities,” affirming an initial determination finding that “[s]uch activities have long been recognized as a domestic industry within the meaning of section 337.”).

In opposition, Apple argues that “Complainants ignore that rainbow® product revenues generally comprise only [REDACTED] of Masimo’s total product revenues in 2020.” *See* RIB at 278. Apple, however, fails to explain why this would be a more appropriate comparison under these circumstances. *See, e.g., Certain Carburetors and Prods. Containing Such Carburetors, Inv. No. 337-TA-1123, Comm’n Op. at 28 (Oct. 28, 2019)* (“Significance is based on the marketplace conditions regarding the articles protected by the Asserted Patents. The fact that a complainant may have substantial sales of other products is not pertinent to this analysis.”).

Accordingly, the undersigned finds that Complainants have demonstrated significant employment of labor or capital with respect to the rainbow® sensors. As discussed above, however, Complainants have not satisfied the domestic industry requirement with respect to the ’127 patent because the current rainbow® sensors have not been shown to practice any claim of the ’127 patent.

IX. CONCLUSIONS OF LAW

Based on the foregoing, and the record as a whole, it is the undersigned’s final initial determination that there has been a violation of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, in the importation into the United States, the sale for importation, and/or the sale within the United States after importation of certain wearable electronic devices with light-based pulse oximetry functionality and components thereof by reason of infringement of claims 24 and 30 of the ’648 patent. There has been no violation of the statute with respect to the asserted claims of the ’501 patent, the ’502 patent, the ’745 patent, or the ’127 patent.

This determination is based on the following conclusions of law:

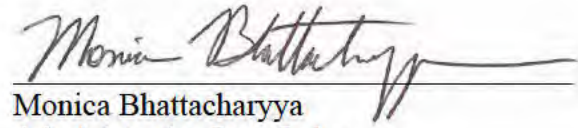
1. The Commission has subject matter jurisdiction over this investigation.
2. The Accused Products have been imported into the United States, sold for importation, and/or sold within the United States after importation.
3. The Commission has *in rem* jurisdiction over the Accused Products.
4. The Accused Products infringe claim 12 of the '501 patent, claims 22 and 28 of the '502 patent, and claims 12, 24, and 30 of the '648 patent.
5. The technical prong of the domestic industry requirement has been satisfied for claim 12 of the '501 patent, claim 28 of the '502 patent, and claims 12, 24, and 30 of the '648 patent.
6. Claim 12 of the '501 patent, claim 28 of the '502 patent, and claim 12 of the '648 patent are invalid.
7. The '501 patent, '502 patent, and '648 patent have not been shown to be unenforceable.
8. The economic prong of the domestic industry requirement has been satisfied with respect to the '501 patent, the '502 patent, and the '648 patent.
9. The Accused Products have not been shown to infringe claims 9 or 27 of the '745 patent.
10. The technical prong of the domestic industry requirement has been satisfied for claim 18 of the '745 patent.
11. Claims 9, 18, and 27 of the '745 patent have not been shown to be invalid.
12. The '745 patent has not been shown to be unenforceable.
13. The economic prong of the domestic industry requirement has been satisfied with respect to the '745 patent.
14. The Accused Products have not been shown to infringe claim 9 of the '127 patent.
15. The technical prong of the domestic industry requirement has been satisfied for claim 9 of the '127 patent.
16. Claim 9 of the '127 patent has not been shown to be invalid.
17. The economic prong of the domestic industry requirement has not been satisfied with respect to the '127 patent.

The undersigned hereby certifies the record in this investigation to the Commission with the undersigned's final initial determination. Pursuant to Commission Rule 210.38, the record further comprises the complaint and exhibits thereto, and the exhibits attached to the parties' summary determination motions and the responses thereto. 19 C.F.R. § 210.38(a).

Pursuant to Commission Rule 210.42(h)(2), this initial determination shall become the determination of the Commission 60 days after the service thereof, unless a party files a petition for review pursuant to Commission Rule 210.43(a), the Commission orders its own review pursuant to Commission Rule 210.44. 19 C.F.R. § 210.42(h)(2).

This initial determination is being issued with a confidential designation pursuant to Commission Rule 210.5 and the protective order in this investigation. Within 10 days of the date of this document, the parties shall submit a joint statement as to whether or not they seek to have any portion of this document deleted from the public version. If the parties do seek to have portions of this document deleted from the public version, they must submit a single proposed public version of this final initial determination with any proposed redactions consistent with the manner specified by Ground Rule 1.9.¹³⁸ The submission shall be made by email to Bhattacharyya337@usitc.gov and need not be filed with the Commission Secretary.

SO ORDERED.


Monica Bhattacharyya
Administrative Law Judge

¹³⁸ Redactions should be limited to avoid obscuring the reasoning underlying the decision. Parties who submit excessive redactions may be required to provide an additional written statement, supported by declarations from individuals with personal knowledge, explaining why each proposed redaction meets the definition for confidential business information in 19 C.F.R. § 201.6(a).